PATENT COOPERATION TREATY



From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 10.11.2000 |
| Applicant's or agent's file reference: P174PCT5 | IMPORTANT NOTIFICATION |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/CA99/00711 | 05/08/1999 | 07/08/1998 |

Applicant: GLYCODESIGN INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

**The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).**

**Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.**

**For further details on the applicable time limits and requirements of the elected Offices, see Volume II of th PCT Applicant's Guide.**

| Name and mailing address of the IPEA/ | Authorized officer |
|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Sälberg, A<br><br>Tel.+49 89 2399-7548 |

Form PCT/IPEA/416 (July 1992)

# PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| P174PCT5 | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/CA99/00711 | 05/08/1999 | 07/08/1998 |
| International Patent Classification (IPC) or national classification and IPC | | |
| C12N15/54 | | |
| Applicant | | |
| GLYCODESIGN INC. et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 07/03/2000 | 10.11.2000 |
| Name and mailing address of the international preliminary examining authority: | Authorized officer |
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Kalsner, I<br>Telephone No. +49 89 2399 8706 |

Form PCT/IPEA/409 (cover sheet) (January 1994)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00711

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
**Description, pages:**

1-32 as originally filed

**Claims, No.:**

1-25 as originally filed

**Drawings, sheets:**

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT** International application No. PCT/CA99/00711

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 4, 5.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4, 5 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard. - -

☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N) Yes: Claims 8, 9, 15, 21-25

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00711

| | | | |
|---|---|---|---|
| | No: | Claims | 1-7, 10-14, 16, 17, 19, 20 |
| Inventive step (IS) | Yes: | Claims | 8, 9, 15, 21, 23, 24 |
| | No: | Claims | 18, 22, 25 |
| Industrial applicability (IA) | Yes: | Claims | 1-25 |
| | No: | Claims | |

2. Citations and explanations
**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
**see separate sheet**

**5 and 14** as well as the vector and host cell of **claims 6 and 7** are not considered novel over the disclosures of D1 and D2.

2.2) **Claims 10 and 11** which relate to a method for preparing a protein and a protein prepared by that method as well as **claims 12 and 13** relating to an antibody are not novel over D1, either.

2.3) **Claims 16 and 17** relating to a method for identifying a substance which associates with a protein as claimed in claim 8 cannot be considered novel in view of the disclosure of D1 (see, eg., p. 30 or p. 31).

2.4) **Claims 19 and 20** which relate to a method for detecting a nucleic acid molecule are not novel over the disclosure of D1 (see, e.g., p. 34).

2.5) **Claims 8, 9, 15, 18 and 21-25** meet the requirements of Art. 33(2) PCT as the subject-matter of these claims is not disclosed as such in any of the available prior art.

**3) Inventive step**

3.1) **Claim 18** does not meet the requirements of Art. 33(3) PCT, as a method for evaluating a compound for its ability to modulate the biological activity of a protein as claimed in claim 8 is not considered to involve an inventive step.

3.2) **Claims 22** does not meet the requirements of Art. 33(3) PCT as the provision of a compound comprising a known product is not considered to involve an inventive step.

3.3) **Claim 25** which relates to a method for preparing an oligosaccharide does not meet the requirements of Art. 33(3) PCT as methods for preparing oligosaccharides using glycosyltransferases are well known in the state of the art. A method which differs merely in the specific glycosyltransferase used, analogues of which, and their activities are known, is not considered to involve an inventive step.

3.4) **Claims 8 and 9** which are directed to an isolated GnT-V-b or GnT-V-c protein defined the specific amino acid sequence are considered to meet the requirements of Art. 33(3) PCT.

3.5) **Claims 15, 21, 23 and 24** are directed to methods relating to a condition believed to be mediated by a protein of the present application. As such methods are neither disclosed nor suggested in the available prior art, **claims 15, 21, 23 and 24** meet the requirements of Art. 33(3) PCT.

**4) Industrial applicability**

With regard to the positive statement concerning industrial applicability of **claims 15, 21, 23 and 24**, which are directed to a method of treatment of the human or animal body,the following should be noted:

For the assessment of these claims on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**Ad Section VIII: Certain observations on the international application**

1) **Claims 1 and 2** refer to nucleic acid sequences which hybridise under stringent conditions to a nucleic acid sequence of SEQ ID NO:1, 3, 5, 9 or 11. Since the hybridisation conditions are not defined , these claims are considered unclear. It should be noted that the nucleic acid sequences disclosed in D1 and D2 comprise fragments of at least 30 (claim 1) or at least 18 (claim 2(iv)) nucleotides which would certainly hybridise under stringent conditions to the listed sequences. Hence, **claims 1 and 2** do not meet the requirements of Art. 6 PCT

2) Furthermore, **claim 3** does not meet the requirements of Art. 6 PCT as it refers to a truncation, an analogue, an allelic or species variation. These terms render the

scope of claims very broad and thus unclear.

3) **Claim 12** does not meet the requirements of Art. 6 PCT in sofar as it refers to an antibody having specificity against a protein as claimed in claim 8. First, according to the guidelines, product claims should be defined by structural features rather than by functional features. Second, claim 8 refers to a protein comprising a specific sequence. This is to be interpreted that the protein, in addition to the specified sequence, also contains further, undefined sequences, which can be other proteins. Hence an antibody directed to any protein has to be considered to fall within the scope of the claim.

4) The application relates to two different GnT-V proteins. In this respect it is not clear, how the various nucleic acid and amino acid sequences are to be assigned to the two proteins. Whereas nucleic acids of SEQ ID NO: 1, 3, 5 and 9 share a high degree of homology, SEQ ID NO:11 is entirely different and must be assumed to encode a completely different protein. SEQ ID NO: 11 (and consequently, SEC ID NO: 12 have thus to be deleted from the claims.